IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application of

Inventor	**:**	**Ivan Salgo**
Application No.	**:**	**10/573,068**
Filed	**:**	**March 23, 2006**
For	**:**	**ULTRASONIC CARDIAC VOLUME QUANTIFICATION**

APPEAL BRIEF

On Appeal from Group Art Unit 3737
Examiner Parikha Solanki Mehta

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I. REAL PARTY IN INTEREST

The real party in interest is Koninklijke Philips Electronics N.V., Eindhoven, The Netherlands by virtue of an assignment recorded June 26, 2006 at reel 017845, frame 0141.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

This application was originally filed with Claims 1-17, which are pending and stand finally rejected by an Office Action mailed December 8, 2009. Claims 1-17 are the subject of this appeal.

IV. STATUS OF AMENDMENTS

No amendments or other filings were submitted in response to the final rejection mailed December 8, 2009. A notice of appeal was timely filed on February 10, 2010.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The subject matter of the claimed invention is a method for ultrasonically measuring the volume of the heart in real time. One of the traditional ways to measure the volume of the left ventricle (LV) of the

heart is by an estimation technique known as "Simpson's rule" or the "rule of disks." In this technique the clinician acquires a 2D long axis image of the LV down the center of the LV. The clinician then traces the endocardial wall in the image, from one side of the mitral valve, to the apex of the chamber, then back to the other side of the mitral valve. The heart chamber delineated by the tracing is then "sliced" horizontally from the outer wall to the septal wall. Each slice line is then taken as the diameter of a disk, and the spacing between slice lines is taken as the thickness of a disk. The volume of each disk is calculated and the disk volumes are summed from the disk on the mitral valve plane to the apex to give an estimate of the chamber volume at the moment when the image was acquired.

The problem with the rule of disks is that it provides an estimate premised on the assumption that the LV chamber is perfectly circular in cross-section, that the diameter line is the diameter of the LV all the way around the disk region. In fact the LV chamber is not circular but irregular in shape depending on where the slice is taken between the mitral valve and the apex of the heart. Furthermore, the shape of the LV chamber is constantly changing as the LV pumps the blood into the aorta and the rest of the body. What the shape is depends on the phase of the heart cycle at which the ultrasound image is acquired. Despite these

limitations of the rule of disks, it remains the most widely accepted technique for estimating heart chamber volume. Its conventional use is as described in the Chenal et al. and Detmer references: acquire images at peak systole and end diastole, when the LV is fully contracted and most greatly expanded, use the rule to estimate volume at these times of minimum and maximum size, then subtract the two to give an estimate of the volume of blood pumped by one contraction of the heart.

The present inventor, Dr. Ivan Salgo, has found a better approach than the rule of disks. It is to acquire two orthogonal image planes through the LV chamber at the same time, at the same phase of the heart cycle. Then instead of having a single diameter of a circular disk, the two images provide two diameters, which Dr. Salgo takes as the major and minor axes of an elliptical disk. Although the cross-section of the LV is not elliptical, the elliptical shape provides a better estimate than the circular assumption. Furthermore, since only two images are acquired at a time, automated border detection can be performed on the two images to automatically delineate the endocardial border of each LV image before another pair of images is acquired. This means that the elliptical estimate of heart chamber volume can be computed and presented to the clinician in real time, as the clinician observes the live heartbeat. If the clinician observes a particular anomaly of interest during the live heart

cycle, the live acquisition can be stopped and the previous image frames in the Cineloop buffer reviewed to carefully diagnose the anomalous behavior of the heart. Dr. Salgo's approach is thus an insightful balance of the desire for accurate measures of the volume of pumped blood and the desire to be able to conduct and observe these measures in real time during the heart cycle.

Independent Claims 1 and 11 are supported by the drawings and specification as seen by reference numerals (#) of the drawings and the specification text (pg., ln) as follows:

1. A method for ultrasonically measuring the volume of a volumetric object of a body such as the heart in real time comprising:

repetitively acquiring ultrasonic images of the heart during a heart cycle in two intersecting image planes which extend through the heart in different directions at substantially the same time with an ultrasound probe; {Fig. 12; pg. 14, lines 1-12}

using an automated processor to define corresponding object borders in the ultrasonic images during the heart cycle; {Fig. 11; pg. 12, lines 12-15; pg. 14, lines 4-6}

producing a plurality of quantified measures of the volume of the heart during the heart cycle from the defined object borders in the different directions; {Fig. 13a; pg. 12, line 26 to pg. 13, line 3} and

displaying measures of the continuous change in the heart volume as the heart beats. {Fig. 12; pg. 14, lines 8-9}

11. A method for ultrasonically measuring the volume of a volumetric object of a body comprising:

acquiring a sequence of ultrasonic images of the heart in real time during a heart cycle in two intersecting image planes at substantially the same time with an ultrasound probe, the intersecting image planes

extending in different directions through the heart volume; {Fig. 12; pg. 14, lines 1-4}

using an automated processor to define corresponding object borders in the ultrasonic images during the heart cycle; {Figs. 11 &13a; pg. 12, lines 12-17; pg. 13, lines 6-13}

producing a real time graphical model of a volumetric region of the heart using the defined object borders; {Fig. 13b; pg. 12, line 26 to pg. 13, line 3; pg. 13, line 14-31} and

producing from the defined object borders a real time measure of the changing heart volume during the heart cycle. {Fig. 12; pg. 14, lines 6-13}

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether Claims 1-17 were correctly rejected under 35 U.S.C. §112, second paragraph, as being indefinite

B. Whether Claims 1-8, 11, 16 and 17 were correctly rejected under 35 U.S.C. §103(a) as being unpatentable over US pat. Pub. No 2002/0072671 (Chenal et al.) in view of U.S. Pat. 6,443,896 (Detmer)

C. Whether Claims 9, 10 and 12-15 were correctly rejected under 35 U.S.C. §103(a) as being unpatentable over Chenal et al. and Detmer and further in view of EP pub. 0961135 (Mumm et al.)

VII. ARGUMENT

A. Whether Claims 1-17 were correctly rejected under 35 U.S.C. §112, second paragraph, as being indefinite

Claims 1-17 were rejected as being indefinite for the recitation of "the continuous change in the heart volume" in Claim 1 without sufficient antecedent basis. However this phrase is supported by the recitation in the preceding claim element of "a plurality of quantified measures of the volume of the heart," which are clearly seen to be the characteristics of the heart volume which are changing as the heart beats.

Claim 11 was said to be indistinct for the recitations of "the heart volume" and "the changing heart volume." It is seen that the subject of the claim is measuring the volume of a volumetric object, and in the acquiring step the heart is specified as being imaged in real time. It is respectfully submitted that one reading this step will clearly understand what "the heart volume" means. Since the claim recites that images of the heart are acquired in different directions through the heart volume in real time, and it is known that the heart is constantly beating, it is respectfully submitted that the phrase "the changing heart volume" is clear to the reader. Accordingly it is respectfully submitted that Claims 1-17 clearly define the present invention.

In paragraph 1 of the Office action the Examiner says that Claim 1 is unclear because the preamble offers the heart as one example of a volumetric object that is measured ("such as the heart"), but the claim elements are specific to the heart ("images of the heart" "measures of the volume of the heart"). It is respectfully submitted that one reading the claim will see that the claim elements are specific to the heart, and that the claim does not cover a body which is not the heart, as the claim elements would not be satisfied if another body is used.

The phrase "the heart" at the beginning of Claims 1 and 11 is used in its normal conversational manner, *e.g.*, "we are going to diagnose the heart" or "look at that image of the heart."

B. Whether Claims 1-8, 11, 16 and 17 were correctly rejected under 35 U.S.C. §103(a) as being unpatentable over US pat. Pub. No 2002/0072671 (Chenal et al.) in view of U.S. Pat. 6,443,896 (Detmer)

Claim 1 describes a method for ultrasonically measuring the volume of a volumetric object of a body such as the heart in real time comprising repetitively acquiring ultrasonic images of the heart during a heart cycle in two intersecting image planes which extend through the heart in different directions at substantially the same time with an ultrasound probe; using an automated processor to define corresponding object borders in the ultrasonic images during the heart cycle; producing

a plurality of quantified measures of the volume of the heart during the heart cycle from the defined object borders in the different directions; and displaying measures of the continuous change in the heart volume as the heart beats. First, it is seen that the claimed method operates in real time to produce and display measures of the continuously changing volume of the heart. The Examiner has taken issue with the term "real time," saying that the term only has meaning in relation to some other event. The Examiner does not understand that the term "real time" is a term of art in diagnostic ultrasound. In ultrasound, "real time" means live imaging, seeing the anatomy as it currently exists and moves. The term is used in contradistinction to static imaging when a single image is acquired and used for diagnosis, or to post-acquisition review and frame by frame playback of a previously acquired and saved image sequence. The measurements in Chenal et al. and Detmer are seen to be performed in post-acquisition review, not in real time. In Chenal et al., a sequence of images is acquired over a heart cycle and the images at end diastole and end systole are picked out and displayed side-by-side as shown in Fig. 8. Borders are then drawn over the static images and the Simpson's rule volume estimation process is applied to each one as explained in paragraph [0040], computing the volume of blood in the LV when the heart is fully expanded and fully contracted. The difference is the

ejection fraction, the volume of blood ejected from the heart by a single heartbeat. The two images are viewed statically on the screen in post-acquisition review as the ejection fraction analysis is performed. This is apparent from the use of "rubberbanding," the manual adjustment of an endocardial border with the mouse, when the clinician is not satisfied with the accuracy of the border tracing. In rubberbanding the clinician drags a part of the border to where the clinician believes the endocardium to be in the image. It is clear that Chenal et al. give no thought to calculating ejection fraction or making any other measurement in real time as live images are produced.

Detmer, like Chenal et al., can acquire images in real time but the ejection fraction measurement is made in post-acquisition review, as it is in Chenal et al. This is clear from col. 5, lines 9-15, where a sequence of live images is saved and later played back frame-by-frame to study the motion of the heart. In doing so the clinician can identify the two frames in which the heart exhibits its maximum and minimum dimensions, end diastole and end systole. The implication is the same as in Chenal et al. From these two frames the ejection fraction can be computed. Like Chenal et al., there is no suggestion of making measurements in real time, only in post-processing review.

Secondly, there is no suggestion in either Chenal et al. or Detmer of producing quantified measures of the heart volume from defined borders of the heart from images extending in different directions through the heart. The ejection fraction computation of Chenal et al. is performed on two images of the same plane of the heart acquired at different times, end diastole and end systole, as shown in their Fig. 8. The two images are temporally, not spatially, different. There is no suggestion of using images acquired at the same time in different directions through the heart. Detmer is likewise silent on producing measurements from borders of the heart in images extending in different directions. Like Chenal et al., Detmer only considers temporally different images when the heart exhibits its "maximum and minimum dimensions," end diastole and end systole, as this is the metric used for ejection fraction. In both patents, a single ejection fraction is calculated for a heartbeat, and is done so with static images in post-processing review. The only suggestion of producing a plurality of quantified measures of the heart from automatically defined borders on differently directed images is found in the present application. For these reasons it is respectfully submitted that Claim 1 and its dependent Claims 2-10 are patentable over Chenal et al. and Detmer.

Claim 11 describes a method for ultrasonically measuring the volume of a volumetric object of a body comprising acquiring a sequence of ultrasonic images of the heart in real time during a heart cycle in two intersecting image planes at substantially the same time with an ultrasound probe, the intersecting image planes extending in different directions through the heart volume; using an automated processor to define corresponding object borders in the ultrasonic images during the heart cycle; producing a real time graphical model of a volumetric region of the heart using the defined object borders; and producing from the defined object borders a real time measure of the changing heart volume during the heart cycle. Chenal et al. describes in paragraph [0040] the use of an automated border detector to trace the endocardial borders of an end diastole image and an end systole image after those images are identified during post-acquisition review of a sequence of heart images. Chenal et al. do not show or suggest defining borders in a pair of simultaneously acquired real time images during the heart cycle. Detmer does not speak to border detection at all. Neither Chenal et al. nor Detmer show or suggest producing a real time graphical model of a volumetric region of the heart using the defined object borders. Neither reference describes a real time graphical model of any sort. Finally, neither Chenal et al. nor Detmer shows or suggests producing from the

defined object borders a real time measure of the changing heart volume during the heart cycle. The ejection fraction computation of Chenal et al. and the left ventricle dimension determination of Detmer are both done in post-acquisition review of an image sequence. For all of these reasons it is respectfully submitted that Chenal et al. and Detmer cannot render Claim 11 and its dependent Claims 12-17 unpatentable.

C. Whether Claims 9, 10 and 12-15 were correctly rejected under 35 U.S.C. §103(a) as being unpatentable over Chenal et al. and Detmer and further in view of EP pub. 0961135 (Mumm et al.)

Claims 9 and 10 depend ultimately from Claim 1 and Claims 12-15 ultimately depend from Claim 11. Mumm et al. was cited for its showing of a wire frame model, shown in Fig. 6 of Mumm et al. It should be noted that Mumm et al. provides none of the elements of Claims 1 and 11 which Chenal et al. and Detmer lack. Like the two earlier references, Mumm et al. perform their operations, not in real time, but during post-acquisition analysis. The acquisition is done by acquiring a plurality of cross-sectional images, digitizing the images and recording them. The recorded digital image data is then transformed into a 3D data set. See paragraph [0016]. "Afterwards a wireframe volume model is created…." Paragraph [0017] The surface contours of an object in the images is detected by surface acquisition or volume rendering. Paragraph [0018]. Defined object borders are not used to form the wire frame model as

recited in Claim 9. Instead, contour points are linked with horizontal and vertical wire lines, which produce the smooth shape as shown in Fig. 6 of Mumm et al. See also paragraph [0036] of Mumm et al. Claim 10 recites that the curves of a wire frame structure comprise ellipses or hemi-ellipses. This is also not found in Mumm et al., Chenal et al. or Detmer. The Examiner attempts to get around this deficiency by stating that "it is well known in the art that the cardiac chambers are generally elliptical in shape." The Examiner cites no authority for this "well known" fact, as indeed it is not true. The LV endocardial borders are irregular in shape, and the shape is constantly changing during the heart cycle. For these reasons it is respectfully submitted that Claims 9 and 10 are patentable over Chenal et al., Detmer and Mumm et al.

Claim 12 describes a wireframe model produced by fitting a series of curves to traced object borders. In Mumm et al., the wireframe model is created by connecting points of special interest with horizontal and vertical wirelines. Claim 13 recites that the curves are a series of ellipses, which is also not found in Mumm et al. or the other citations. Claim 14 recites fitting a surface to a wireframe model. Mumm et al. do the opposite. They detect contours by using surface acquisition, but then do nothing further with the detected surfaces. The wireframe model is never fitted with a surface. See paragraphs [0018] and [0036] of Mumm et al.

And as previously stated, Mumm et al. provides none of the elements of Claim 11 which Chenal et al. and Detmer lack. For all of these reasons it is respectfully submitted that Claims 12-14 are patentable over Chenal et al., Detmer, and Mumm et al.

VIII. CONCLUSION

Based on the law and the facts, it is respectfully submitted that Claims 1-17 are clear and definite, and that Claims 1-17 are patentable over any combination of Chenal et al., Detmer and Mumm et al. The real time ultrasonic measuring techniques of the present invention are not shown or suggested by any of these references. Accordingly, it is respectfully requested that this Honorable Board reverse the grounds of rejection of Claims 1-17 of this application which were stated in the December 8, 2009 Office action being appealed.

Respectfully submitted,

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April 7, 2010

APPENDIX A: CLAIMS APPENDIX

The following Claims 1-17 are the claims involved in this appeal.

1. (previously presented) A method for ultrasonically measuring the volume of a volumetric object of a body such as the heart in real time comprising:

repetitively acquiring ultrasonic images of the heart during a heart cycle in two intersecting image planes which extend through the heart in different directions at substantially the same time with an ultrasound probe;

using an automated processor to define corresponding object borders in the ultrasonic images during the heart cycle;

producing a plurality of quantified measures of the volume of the heart during the heart cycle from the defined object borders in the different directions; and

displaying measures of the continuous change in the heart volume as the heart beats.

2. (previously presented) The method of Claim 1, further comprising producing a graphical model of the volumetric object using the defined object borders; and wherein producing quantified measures further comprises producing quantified measures using the graphical model.

3. (previously presented) The method of Claim 1, wherein displaying further comprises producing a display comprising real time images from the two intersecting image planes with a visually highlighted defined object border in each image and a quantified measure using the defined object border of the images.

4. (original) The method of Claim 3, wherein producing a display comprising a quantified measure further comprises producing a display of changes in the volumetric object as a function of time.

5. (previously presented) The method of Claim 3, wherein the display of changes in the volumetric object as a function of time comprises a graphical display, a numerical display or both a graphical and numeric display.

6. (previously presented) The method of Claim 1, wherein acquiring ultrasonic images comprises acquiring ultrasonic images of a chamber of the heart,

wherein the corresponding object borders comprise the wall of the chamber of the heart.

7. (previously presented) The method of Claim 2, further comprising producing a display comprising real time images from the two intersecting image planes with a visually highlighted defined object border in each image, a real time graphical model using the defined object borders, and a quantified measure using the defined object border of the images.

8. (previously presented) The method of Claim 2, wherein producing quantified measures further comprises using the graphical model to produce a volumetric measure by the rule of disks.

9. (previously presented) The method of Claim 2, wherein producing a graphical model comprises fitting a series of curves to a wire frame structure formed by the defined object borders.

10. (original) The method of Claim 9, wherein the curves comprise ellipses or hemi-ellipses.

11. (previously presented) A method for ultrasonically measuring the volume of a volumetric object of a body comprising:

acquiring a sequence of ultrasonic images of the heart in real time during a heart cycle in two intersecting image planes at substantially the same time with an ultrasound probe, the intersecting image planes extending in different directions through the heart volume;

using an automated processor to define corresponding object borders in the ultrasonic images during the heart cycle;

producing a real time graphical model of a volumetric region of the heart using the defined object borders; and

producing from the defined object borders a real time measure of the changing heart volume during the heart cycle.

12. (previously presented) The method of Claim 11, wherein using an automated processor further comprises using an automated processor to automatically trace corresponding object borders in the ultrasonic images; and wherein producing a graphical model comprises producing a wireframe model by fitting a series of curves to the traces in their corresponding image planes.

13. (original) The method of Claim 12, wherein the series of curves further comprise a series of ellipses.

14. (previously presented) The method of Claim 12, wherein producing a graphical model further comprises fitting a surface to the wireframe model.

15. (previously presented) The method of Claim 12, wherein producing a real time measure further comprises producing quantified measures of the graphical model by the rule of disks.

16. (previously presented) The method of Claim 11, further comprising producing a display comprising real time images from the two intersecting image planes with a visually highlighted defined object border in each image and a real time graphical model using the defined object borders.

17. (previously presented) The method of Claim 11, wherein acquiring comprises acquiring ultrasonic images of the volumetric object in two or more intersecting image planes at substantially the same time with an ultrasound probe.

APPENDIX B: EVIDENCE APPENDIX

None. No extrinsic evidence has been submitted in this case.

APPENDIX C: RELATED PROCEEDINGS APPENDIX

None. There are no related proceedings.